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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/459,141 06/02/95 BERMAN

F P023306

EXAMINER

HM22/0207

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ART UNIT

PAPER NUMBER

26

1645
DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/459,141

Applicant(s)
Phillip Berman

Examiner
Brett Nelson

Group Art Unit
1648



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 2, 6-8, 14, and 15 is/are allowed.
- ☒ Claim(s) 1, 3-5, and 9-13 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant is advised that the Notice of Allowance mailed Jan. 22, 1999 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a Deposit Account.
2. Prosecution on the merits of this application is reopened on claims 1-15 considered unpatentable for the reasons indicated below:

Claim Rejections - 35 USC § 112

3. Claims 1, 3-5 and 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of immunizing an individual against herpes simplex 1 or 2 comprising administering a vaccine comprising a truncated, membrane free glycoprotein D polypeptide of herpes simplex virus, does not reasonably provide enablement for a method of immunizing against all pathogens or a method of immunizing against herpes simplex virus comprising administering a composition which comprises a membrane free derivative of a membrane bound protein, a truncated membrane-free derivative of a membrane-bound polypeptide or membrane bound polypeptide other than glycoprotein D. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of immunizing a patient against any pathogen or to a method of immunizing a patient against herpes by administering a truncated, membrane free derivative of a membrane bound polypeptide. The broadest claim encompasses all viral, bacterial, fungal and protozoan species. The specification lacks sufficient guidance and teaching to enable entire scope of the claims. Moreover, the specification does not contain sufficient guidance or teaching to enable a method of immunizing a patient against herpes by administering a truncated, membrane free derivative of a membrane bound polypeptide other than glycoprotein D. The specification states on page 46 that the function of the glycoproteins C and F are unknown and that it is not clear that gC and gF are indispensable to the viruses during in vivo infection of the human and the establishment of latency. While the specification describes sequence homologies between gC and gF, the specification lacks enablement to show a correlation between gC, gF or other herpes glycoproteins and gD, such that one might reasonably expect similarity in structure and function. Thus it would appear that the role of the gC, gF or other glycoproteins in generating protective immune responses has also not been clearly defined and one would not be able to reasonably predict success with a vaccine against herpes simplex virus comprising glycoproteins other than glycoprotein D absence evidence of its function.

While the specification contains examples showing administering glycoprotein D to mice, the specification does not contain any teaching or guidance which shows that the results obtained

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with glycoprotein D correlate to other herpes glycoproteins. Moreover, Mester et al. (Rev. Inf. Dis. 1991) state that misleading results can be obtained from the mouse used as a model to identify proteins or peptides that are presumed to be important for inducing immunity to HSV.

In view of all of the above, it is determined that the specification is not commensurate in scope with the invention as claimed.


4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)308-4426. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NELSON/bn
December 17, 1999



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600